



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
---------------	-------------	----------------------	---------------------

07/954,772 09/30/92 ENGELHARDT

18N1/1104

ENZO DIAGNOSTICS INC.
C/O ENZO BIOCHEM, INC.
575 FIFTH AVENUE (18TH FLOOR)
NEW YORK, NEW YORK 10017

D ENZ-5(D8)(C)

EXAMINER

MARSCHER, A

ART UNIT

PAPER NUMBER

1807

10

DATE MAILED:

11/04/93

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

- ☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- ☒ Notice of References Cited by Examiner, PTO-892.
- ☒ Notice re Patent Drawing, PTO-948.
- ☐ Notice of Art Cited by Applicant, PTO-1449.
- ☐ Notice of Informal Patent Application, Form PTO-152.
- ☐ Information on How to Effect Drawing Changes, PTO-1474.
- ☐

Part II SUMMARY OF ACTION

1. ☒ Claims 240-282 are pending in the application.

Of the above, claims _____ are withdrawn from consideration.

2. ☒ Claims 1-239 have been cancelled.

3. ☐ Claims _____ are allowed.

4. ☒ Claims 240-282 are rejected.

5. ☐ Claims _____ are objected to.

6. ☐ Claims _____ are subject to restriction or election requirement.

7. ☒ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable, ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner, ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed on _____, has been ☐ approved, ☐ disapproved (see explanation).

12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received, ☐ not been received.
☐ been filed in parent application, serial no. _____; filed on _____

13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

EXAMINER'S ACTION

Serial No. 07/954,772

- 2 -

Art Unit: 1807

The numbering of claims is not accordance with 37 C.F.R. § 1.126. The original numbering of the claims must be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When claims are added, except when presented in accordance with 37 C.F.R. § 1.121(b), they must be renumbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 2-44 have been renumbered 240-282, respectively.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The title is so broad that it lacks any significant indication as to the claimed invention.

If applicant desires priority under 35 U.S.C. § 120 based upon a parent application, specific reference to the parent application must be made in the instant application. It is noted that this appears as the first sentence of the specification following the title. Status of the parent application (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "Patent No." should follow the filing date of the parent application. If a parent application has become abandoned, the expression "abandoned" should follow the filing date of the parent application.

It is noted that a PTO Form 1449 has been filed 6/28/93 but that it has not been executed nor a copy enclosed since no copies of the references listed thereon have been filed in the instant application.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 240-282 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to hybridization conditions that permit hybridization between the probe and target analyte. The broad term "contacting" as cited, for example, in line 3 of claim 240 is not instantly supported beyond hybridization practice. There is no instant disclosure or suggestion for analyte detection other than via hybridization practice as noted above. It is noted also that line 1 of claim 240 is broadly directed to "analyte" detection which is not supported beyond nucleic acid target detection. Also the last line of claim 240 cites the detection via "bound" practice. This also lacks instant support beyond "hybridized" practice. See M.P.E.P. §§ 706.03(n) and 706.03(z).

Claims 275-277 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to antibiotic/bacterium species combinations that are instantly enabled. Not all possible combinations as suggested by these claims are instantly enabled. See M.P.E.P. §§ 706.03(n) and 706.03(z).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 240-244, 254-256, 259-263, 265, 267-273, 278, and 280 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Kourilsky et al.

Kourilsky et al. disclose hybridization assay methods using RNA probes labeled with various label types such as disclosed on page 1, line 38-53. Antibody and enzyme label moieties are also disclosed by Kourilsky et al. for example on page 5, lines 18-20. Electron dense labels are disclosed via mercury as given on page 2, lines 47-52. It is noted that instant claim 240 cites Sig moieties linked either to the sugar moiety or phosphate moiety with minimal limitation as to the signal moiety as being detectable. Kourilsky et al. also cite a variety of targets inclusive of genetic diseases, bacterial infections, etc. Taken as a whole Kourilsky et al. reads on the broadly claimed instant invention.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which

the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claims 272-277 are rejected under 35 U.S.C. § 103 as being unpatentable over Kourilsky et al. taken in view of Falkow et al.

The instant invention is summarized in the above rejection under § 102(b) and includes the detection of various etiological agents including antibiotic resistance gene targets of various bacteria.

Kourilsky et al. discloses the basics of the instant invention but lacks specific antibiotic resistance gene target detection via hybridization assay but via its generic nucleic acid target disclosure supplies motivation and a reasonable expectation of success for generic nucleic acid targets.

Falkow et al. disclose the detection of various bacterial targets via antibiotic resistance genes disclosed in the abstract as well as the disclosure as a whole.

Thus, it would have been obvious to someone of ordinary

skill in the art at the time of the instant invention to practice hybridization assay detection of etiological agents via the bacterial antibiotic resistance genes because Kourilsky et al. discloses the basic detection methodology and Falkow et al. adds said antibiotic resistance genes of bacteria as nucleic acid targets having a reasonable expectation of success in such hybridization assays.

Claims 240-282 are rejected under 35 U.S.C. § 103 as being unpatentable over Kourilsky et al.

The instant invention broadly is directed to methods using a variety of covalent linkages between a generic "Sig" moiety and hybridization probes used to detect generic targets or wide scope.

Kourilsky et al. discloses the basic hybridization assay using probes labeled in a variety of ways as discussed in the above rejections. It is noted that claim 240 cites "Sig" linkages to every portion of a nucleotide residue only excluding very specific base moiety linkages. This broad "Sig" disclosure permits Kourilsky et al. to suggest Sig moieties that may be as simple as labeled segments of probes which may or may not participate in direct hybridization. Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to practice the instant invention given a wide generic set of labels with Sig linked at least at one of the instantly claimed linkages given broad linkages as disclosed by Kourilsky et al.

Serial No. 07/954,772

- 7 -

Art Unit: 1807

Ward et al. is cited on the enclosed PTO Form 892 as being of interest in the instant application.

No claim is allowed.

Papers related to this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to Group 180 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

The CM1 Fax Center number is (703) 308-4227 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703) 308-3894.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

AM

A. MARSCHEL:am
November 1, 1993


MARGARET PARR
SUPERVISORY PATENT EXAMINER
GROUP 1800